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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/266,889	03/12/99	SCHNEIDER	M 1201-71

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HM12/0918

EXAMINER

HOLLINDEN, G

ART UNIT	PAPER NUMBER
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1619

DATE MAILED: 09/18/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/266,889	SCHNEIDER ET AL.	
	Examiner	Art Unit	
	Gary E Hollinden, Ph.D.	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1) ☐ Responsive to communication(s) filed on ____.

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-26 is/are pending in the application.

4a) Of the above claim(s) ____ is/are withdrawn from consideration.

5) ☐ Claim(s) ____ is/are allowed.

6) ☒ Claim(s) 1-26 is/are rejected.

7) ☐ Claim(s) ____ is/are objected to.

8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:

1. ☐ received.

2. ☐ received in Application No. (Series Code / Serial Number) ____.

3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) 16) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____	18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 20) <input type="checkbox"/> Other:
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Claims 1-26 have been presented for examination and will be reviewed on their merits.

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Claims 12-26 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 12-26 are confusing because they use "open" language which would imply other ingredients in the gas; however, claim 1 appears to claim a single gas not a mixture. These claims could be made proper by substituting "is" for "comprises".

Effective Priority Date

The instant application is a continuation-in-part of four separate chains of applications. Some of the sub-genera now claimed is not found in all of the applications to which this application claims priority. The effective priority date of any given claim is the date at which Applicant first conveyed the inventive concept of the claim as a whole. For example, if Applicant conveyed the concept of using a phospholipid mixture as the shell material in one chain of applications and conveyed the concept of using a fluorinated gas in another chain of applications but did not convey the concept of combining the together until the instant application, then the effective priority date of that claim would be that of the instant application. Also, if a claim set forth a genus of three sub-general of gases which can be used and the three sub-genera were first conveyed in different priority applications, then effective priority date for the claim as a whole would be the effective priority date of the sub-genus which was most recently conveyed since that would be the date that the genus, as a whole, was conveyed to the public.

Another important point is that the effective priority date of a dependent claim would usually be no earlier than the effective priority date of its base claim(s) since a dependent claim includes all the limitations and particulars of the base

claim(s). An exception would be if the dependent claim set forth a specific combination which was explicitly disclosed in an earlier application.

Set forth below are the apparent¹ effective priority dates for the genera and sub-genera now claimed. As noted above, the effective priority date of any given claim can be no earlier than the most recent effective priority date of any component of the claim and may be more recent still since the actual effective priority date is when the combination of all the components (i.e. the invention as a whole) was first conveyed.

1) The first disclosure of the sub-genus embraced by the term Freon® was in EP90810262, filed April 2, 1990, therefore, the inventive concept of using any Freon® as a gas was first conveyed in said application.

2) The first disclosure of the term "halogenated hydrocarbon" was in EP 92810046, filed January 23, 1992; therefore, the inventive concept of using any halogenated hydrocarbon as a gas was first conveyed in said application.

3) The first disclosure of the sub-genus embraced by the term "fluorinated compounds" is in the instant application, therefore, the inventive concept of using any fluorinated gas was first conveyed in the instant application, filed March 5, 1999.

4) The first disclosure of stabilizing the microbubbles with a surfactant was in EP90810262, filed April 2, 1990, therefore, the inventive concept of using a surfactant was first conveyed in said application. Surfactants are also taught as part of the invention set forth in EP 93810885, filed December 15, 1993 and in EP 90810367, filed May 18, 1990. However, EP 92810046 does not appear to teach the concept of using a surfactant, per se, although it does teach using substances that would be encompassed by the term surfactant.

5) The first disclosure of the species SF₆, SeF₆, CF₄, CBrF₃, C₄F₈, CClF₃, C₂F₆, C₂ClF₅, CClBrF₂, CCl₂F₄, CBr₂F₂, and C₄F₁₀ was in EP 92810046, filed

¹By "apparent" is meant that it is the first disclosure of the sub-genus or combination that the Examiner was able to find. Applicant is encouraged to do their own research to ensure that the earliest actual priority dates are set forth in the written record.

January 23, 1992; therefore, the inventive concept of using these species was first conveyed in said application.

6) Since EP 92810046 fails to teach the concept of using a surfactant, the first teaching of using the gases SF_6 , SeF_6 , CF_4 , CBrF_3 , C_4F_8 , CClF_3 , C_2F_6 , C_2ClF_5 , CClBrF_2 , CCl_2F_4 , CBr_2F_2 , and C_4F_{10} in combination with a surfactant is in the instant application, filed March 5, 1999. Therefore, the inventive concept of using one of the above gases in combination with the entire genus embraced by the term surfactant was first conveyed in the instant application, filed March 5, 1999.

7) The first disclosure of the species C_3F_8 , C_4F_6 , $\text{C}_2\text{Cl}_2\text{F}_4$, C_5F_{10} , C_5F_{12} , SeF_6 is in the instant application, therefore, the inventive concept of using any these gases was first conveyed in the instant application, filed March 5, 1999. The gases C_3F_8 , C_4F_6 , $\text{C}_2\text{Cl}_2\text{F}_4$, C_5F_{10} were disclosed in EP 93810885, filed December 15, 1993 but only as part of a mixture of gases. Therefore, the inventive concept of the combination of a single one of these species in combination with a surfactant was not conveyed in EP 93810885.

8) The first disclosure of the genus of methods embraced by the term "contrast agent" is in the instant application, therefore, the inventive concept of using any contrast agent was first conveyed in the instant application, filed March 5, 1999. The benefit applications only teach their compositions for ultrasonic imaging. The artisan, looking to their specifications, would have no reason to believe that Applicant intended to possess any other use for their microbubble compositions other than ultrasonic imaging.

9) The first disclosure of using a viscosity modifier, was in EP90810262, filed April 2, 1990, therefore, the inventive concept of using said agents was first conveyed in said application. Of course, the inventive concept of using these viscosity modifiers with a particular sub-genus of gases was not conveyed until the two were taught as being used together. In the case of these agents with a Freon®, it was in EP90810262, filed April 2, 1990. For said agents and the sub-genus "halogenated hydrocarbon", it was in EP 92810046, filed January 23, 1992. There does not appear a disclosure of viscosity modifiers in EP93810885

or EP92810046. Therefore, the first disclosure of a viscosity modifier with a gas mixture is in the instant application, filed March 5, 1999.

In accordance with the effective priority dates set forth above, it appears that all of the pending claims include a genus or sub-genus which has an effective priority date which is no earlier than the filing date the instant application. Therefore, all of the instant claims have as an effective priority date the filing date of the instant application.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

"A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent."

Claims 1-26 are rejected under 35 U.S.C. § 102(b,e) as being anticipated by Klaveness et al. (5,558,856; PTO-892 dated 9/15/00), Unger et al., (5,776,429; PTO-892 dated 9/15/00), Unger (5,585,112; PTO-892 dated 9/15/00), Quay (5,558,094; PTO-892 dated 9/15/00) and Quay (5,393,524; PTO-892 dated 9/15/00).

These claims appear to be directed towards a method of ultrasonic imaging comprising administering a composition comprising microbubbles stabilized by a surfactant, and a gas, wherein the gas (in its broadest definition) is a fluorine containing gas.

Klaveness et al., Unger et al., Unger, Quay and Quay each teach suspensions of microbubbles which contain various surfactants including lipids and further teach a number of fluorinated gases, including essentially all of the claim designated gases. Klaveness et al. (examples 19-23; table II) teach the combination of a lipid (i.e. a surfactant) with a polysaccharide as well as a fluorine containing gas. Unger ('429; col. 2, lines 48-67; examples 1, 6, and 7) and Unger ('112; col. 25, lines 4-14;

examples 1, 3, 4, 5, and 10) teach surfactant stabilized microspheres which contain a fluorinated gas. Quay ('524, col. 7, line 59 - col. 8, line 50; Table II; col. 15, lines -62) and Quay ('094) teach microbubbles stabilized with other materials than lipids as well as generally teaching a variety of shell material. Quay and Quay teach several fluorinated gases as well as specific example containing a fluorinated gas and a surfactant.

Therefore, Klaveness et al., Unger et al., Unger, Quay and Quay fully anticipate the instant claims.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-26 are rejected under 35 U.S.C. § 103 as being unpatentable over Klaveness et al. (5,558,856; PTO-892 dated 9/15/00), Unger (5,776,429; PTO-892 dated 9/15/00), Unger (5,585,112; PTO-892 dated 9/15/00) and Quay (5,393,524; PTO-892 dated 9/15/00).

These claims appear to be directed towards a method of ultrasonic imaging comprising administering a composition comprising microbubbles stabilized by a surfactant, and a gas, wherein the gas (in its broadest definition) is a fluorine containing gas.

Klaveness et al., Unger et al., Unger, Quay and Quay each teach the use of microbubbles which contain various surfactants including lipids and further teach a number of fluorinated gases, including essentially all of the claim designated gases for ultrasonic imaging. Klaveness et al. (examples 19-22; table II) teach the

combination of a lipid (i.e. a surfactant) with a polysaccharide as well as a fluorine containing gas. Unger ('429; col. 2, lines 48-67; examples 1, 6, and 7) and Unger ('112; col. 25, lines 4-14; examples 1, 3, 4, 5, and 10) teach surfactant stabilized microspheres which contain a fluorinated gas. Quay ('524, col. 7, line 59 - col. 8, line 50; Table II; col. 15, lines -62) and Quay ('094) teach microbubbles stabilized with other materials than lipids as well as generally teaching a variety of shell material. Quay and Quay teach several fluorinated gases as well as specific example containing a fluorinated gas and a surfactant.

Since Klaveness et al., Unger et al., Unger, Quay and Quay are all drawn to using microbubbles containing a (fluorinated) gas for ultrasonic imaging, all are considered to be in the same field of endeavor.

While Klaveness et al., Unger et al., Unger, Quay and Quay fail to teach all possible combinations of a surfactant with a fluorinated gas, it would have been obvious to those of ordinary skill in the art that essentially any such combination could be made since the cited prior art broadly teaches the combination of various surfactants with fluorinated gases as well as providing specific examples thereof. One of ordinary skill would have been motivated to substitute essentially any known surfactant with a fluorinated gas to produce the most stable microbubble for ultrasonic imaging.

The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Claims 1-26 are rejected under 35 U.S.C. § 102(e) as being anticipated by Lohrmann et al. (US 5,716,597; PTO-892 dated 9/15/00).

These claims appear to be directed towards a composition comprising a suspension comprising a surfactant and a gas, wherein the gas is a fluorine containing gas.

Lohrmann et al. (example 11) teach compositions comprising both a protein (albumin) and a surfactant and other compositions comprising fluorinated gases

with surfactants (examples 4, 7, and 10) as well as method of preparing them and using them for ultrasonic imaging. Therefore, the instant claims are anticipated.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-26 are rejected under 35 U.S.C. § 103 as being unpatentable over Lohrmann et al. (US 5,716,597; PTO-892 dated 9/15/00).

These claims appear to be directed towards a composition comprising a suspension comprising a surfactant and a gas, wherein the gas is a fluorine containing gas.

Lohrmann et al. (example 11) teach compositions comprising both a protein (albumin) and a surfactant and other compositions comprising other polymers with surfactants (examples 4, 7, and 10) as well as method of preparing them and using them for ultrasonic imaging.

While Lohrmann et al. fail to teach all possible halogenated hydrocarbons, it would have been obvious to those of ordinary skill in the art that essentially any halogenated hydrocarbon could be used because Lohrmann et al. teach a large number of specific halogenated hydrocarbons as well as teaching that any low solubility gas may be used. One of ordinary skill would have been motivated to substitute any gas which met the criteria of being poorly soluble and would have been especially motivated to select from the genus of halogenated hydrocarbons since so many specific examples from said genus were provided.

The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Claims 1-26 are rejected under 35 U.S.C. § 103 as being unpatentable over Albayrak et al. (5,730,954; PTO-892 dated 9/15/00) and Rössling et al. (5,593,687; PTO-892 dated 9/15/00).

These claims appear to be directed towards a composition comprising a suspension comprising a surfactant and a gas, wherein the gas is a fluorine containing gas.

Albayrak et al. (col. 7, lines 8-23) and Rössling et al. (col. 3, lines 8-29; col. 4, lines 22-23) both teach the use of microbubbles which contain various surfactants including lipids and further teach a number of fluorinated gases for ultrasonic imaging.

Since Albayrak et al. and Rössling et al. are all drawn to using microbubbles containing a (fluorinated) gas for ultrasonic imaging, all are considered to be in the same field of endeavor.

While Albayrak et al. and Rössling et al. fail to teach all possible combinations of a surfactant with a fluorinated gas, it would have been obvious to those of ordinary skill in the art that essentially any such combination could be made since the cited prior art broadly teaches the combination of various surfactants with fluorinated gases as well as providing specific examples thereof. One of ordinary skill would have been motivated to substitute essentially any known surfactant with a fluorinated gas to produce the most stable microbubble for ultrasonic imaging.

Claims 1-26 are rejected under 35 U.S.C. § 103 as being unpatentable over Rössling et al. (5,501,863; PTO-892 dated 9/15/00), Tickner '251 (PTO-892 dated 9/15/00), Tickner et al. '885 (C; PTO-892 dated 9/15/00), Illum (PTO-892 dated 9/15/00), Albayrak (5,730,954; PTO-892 dated 9/15/00) Glajch et al. (5,147,631;

PTO-892 dated 9/15/00), Swanson (PTO-892 dated 9/15/00), and Hilmann et al. (4,466,442; PTO-892 dated 9/15/00) in view of Lincoff et al. (PTO-892 dated 9/15/00), Lincoff et al. (PTO-892 dated 9/15/00), Gardner et al. (PTO-892 dated 9/15/00) Jacobs (PTO-892 dated 9/15/00) and the Dupont Technical Bulletin (PTO-892 dated 9/15/00).

These claims appear to be directed towards a composition comprising a suspension comprising a surfactant and a gas, wherein the gas is a fluorine containing gas.

Each of Rössling et al. Tickner '251, Tickner et al. '885, Glajch et al., Swanson, Ryan et al. and Hilmann et al. teach various types of gas filled microspheres. Each of Rössling et al. Tickner '251, Tickner et al. '885, Glajch et al., Swanson further teach that fluorinated gases may be used. Rössling et al. specifically teach as potential gases both sulfur hexafluoride and a low molecular weight fluorinated hydrocarbon, both of which are poorly soluble in water. Tickner and Tickner et al., teach microbubbles enclosed in various interfacial membranes along with a genus of fluorinated gases; namely Freon[®]. The term Freon[®] actually represents a well defined class of small halogen containing molecules. The Dupont Technical Bulletin teaches that fluorinated molecules are a well known and explicitly exemplified sub-group of the compounds encompassed by the term Freon[®]. In particular, the claim designated perfluoroethane, perfluoropropane, and perfluorocyclobutane are Freons[®] (Freon[®]-116, Freon[®]-218 and Freon[®]-318, respectively). Consequently, when taken with the Dupont Technical bulletin, the disclosures of Tickner and Tickner et al. clearly teach fluorinated chemicals. Illum et al. (page 5; examples 2 and 4-8) teach the formation of microbubbles using poorly soluble volatile gases and further teach that the gas inside the microbubbles would be a mixture of air and the volatile gas. Swanson et al. particularly teach perfluorocarbons that are gases at 37° C². Albayrak et al. teach several poorly soluble gases including SF₆ and further teach that said gases would be formed in an albumin containing solution. Administrative notice is taken that the albumin in the solution would be fully expected to assemble at the air liquid interface. Glajch

²Which would include C₁F₄ - C₅F₁₂.

et al. (col. 6, lines 58-66) specifically teach the use of the claim designated perfluoromethane and perfluoroethane as well as other insoluble gases such as helium and argon. Lincoff et al., Lincoff et al., Gardner et al. and Jacobs teach the desirability of using small perfluorocarbon molecules in vivo because of the stability, safety, acceptable acoustic properties. In addition, the Lincoff publications specifically teach perfluoroethane, perfluoropropane, and perfluorobutane and Jacobs specifically teaches SF₆.

Since each of Rössling et al., Swanson, Tickner, Tickner et al., Albayrak et al., Glajch et al. Swanson et al. Ryan et al. and Hilmann et al. teach that their microbubble compositions would be useful for ultrasonic imaging, all of them may be considered to be in the same field of endeavor. While the Lincoff et al. publications and Gardner et al. are not directed towards ultrasonic imaging and thus could not be considered to be within the same field of endeavor as the references cited above, they specifically address the importance and the usefulness of small perfluorocarbon gases in vivo; giving particular attention to the long persistence of their effect due to their insolubility. Thus, they are pertinent to the problem that inventors in the ultrasonic imaging arts were trying to solve at the time of the invention. Tickner et al. (col. 4, lines 16-29) and Rössling et al. specifically address the importance of finding a gas which has a long duration in the blood and note low solubility as a criteria. In addition, Jacobs serves as a bridge between the ultrasonic imaging arts and the therapeutic art in that Jacobs also is primarily concerned with the therapeutic uses of the perfluorocarbon gases yet also teaches that ultrasonic imaging techniques may be applied to bubbles of perfluorocarbon gases. While the type of large bubble ultrasonic imaging used by Jacobs is not the same as microbubble imaging, it still serves as a bridge in that a person of ordinary skill, while searching through the ultrasonic imaging literature, would find a cross reference to Jacobs and thus find further information about the duration problem they were attempting to solve. It is also important to note that Lincoff et al., Lincoff et al., Gardner et al. and Jacobs teach that small fluorinated molecules are safe in quantities that are orders of magnitude beyond the quantities

injected in a bolus of microbubbles. This is also a problem that would be extremely pertinent when determining what gas to use in *in vivo* ultrasonic imaging.

While the prior art references fail to particularly teach each and every gas that would be poorly soluble, it would have been obvious to those of ordinary skill in the art that essentially any poorly soluble gas could be used because the prior art references teach that a large and representative list of poorly soluble gases are useful for ultrasonic imaging. One of ordinary skill would have been motivated to particularly select poorly soluble molecules from among the possible gases to be used in each of Rössling et al. Tickner '251, Tickner et al. '885, Glajch et al., Swanson and Albayrak et al. because Lincoff et al., Lincoff et al., Gardner et al. and Jacobs teach the desirability of using poorly soluble gases in *in vivo* ultrasonic applications

The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Claims 1-26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. patent no. 5,413,774, 5,578,292, 5,686,060, 5,556,610, 5,445,813, 5,556,610, 5,518,991, 5,597,549, 5,567,414, 5,711,933, 5,380,519, 5,531,980, 5,271,928, 5,643,553, 5,658,551, and 5,711,933. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are sufficiently broad in their recitation of the halogenated hydrocarbon gas and phospholipid membrane to be used so as to encompass the previously patented claims.

Claims 1-26 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending application serial no. 08/740,653, 08/832,950, 08/637,346, 09/115,963, 08/848,912, 09/021,367, 08/855,055, 08/810,447, 08/910,149, 08/910,152, 08/947,196, 08/893,371, 09/002,710, 09/021,150, 09/225,293, 09/253,536, 09/263,105, 09/266,889, 09/401,829, 09/401,835, 09/401,836, 09/401,837,

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09/401,838. Although the conflicting claims are not identical, they are not patentably distinct from each other because all the above patents are drawn to compositions comprising phospholipids and gases for ultrasonic imaging..

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The obviousness-type double patenting rejection, whether of the obviousness type or non-obviousness type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent³.

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. 3.73(b).

The various declarations filed with the instant application have been considered but since they are drawn to a request for interference, the arguments contained therein are considered moot until such time that there are allowable claims.

In view of the objections /rejections to the pending claims set forth above, no claims may be allowed at this time.

The processing of this application can be expedited by providing the following information or changes in your next amendment:

- Proper cross-reference to related applications for which priority is claimed under 35 U.S.C. § 120 in the first paragraph of the specification - including current status (M.P.E.P. 201.11)
- Early filing of an Information Disclosure Statement that includes a PTO-1449 form wherein the document number, publication date, inventor, country of publication, and US patent classification is listed for each patent document and wherein the author, title, journal, volume, issue (if known), pages, and year of publication is listed for all journal references (M.P.E.P. 609). A timely prior art disclosure by the Applicant aids in a speedy prosecution and helps to insure that the patent granted is both valid and enforceable.

³*In re Thorington*, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 214 USPQ 761 (CCPA 1982); *In re Longi*, 225 USPQ 645 (CA FC 1985); and *In re Goodman*, 29 USPQ 2010 (CA FC 1993).

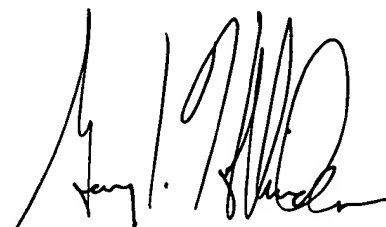
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- A descriptive title (M.P.E.P. 606 and 606.01). Please note that 1-2 word titles are generally unacceptable.
- Ensuring that each of the drawings presented (if any) are described in the brief description of the drawings. Please note that if a drawing has more than one figure in it (e.g. Figures 1A and 1B), each of the figures must be individually described.
- An abstract which is descriptive of the disclosed invention and contains the chemical structure of the active ingredient(s).
- Correction of any ambiguities in the specification which may lead to a printer inquiry, such as blank spaces which appear to be omissions.
- Correction of any typographical errors in the application.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to the Group 1600 fax machine at 703/308-4556. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30; November 15 1989.

Any inquiry concerning this Office Action or any earlier Office Actions in this application should be directed to Dr. Gary E. Hollinden whose telephone number is 703/308-4521. Dr. Hollinden's office hours are from 6:30 am to 3:00 pm on Monday through Friday.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is 703/308-1235.

A handwritten signature in black ink, appearing to read 'Gary E. Hollinden', is positioned above the printed name.

Gary E. Hollinden, Ph.D.
Primary Examiner
Group 1600